

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Guided Tour: Interactive Early Mock-up

Introduction

The ClinicalTrials.gov Results Registration System (RRS), to be implemented by September 2008, is intended to allow users to fulfill the requirements of the “basic results” provisions of Section 801 of the Food and Drug Administration Amendments Act ([Pub. L. 110-85](#)). Eventually, there will be two methods of submitting data: (1) Interactive Web-based data entry of results or (2) Automated, batch upload of results data files.

This guided tour provides a step-by-step review of an *early mock-up* of the interactive Web-based RRS data entry system (available at <http://prsinfo.clinicaltrials.gov/rrs-mockup-intro.html>). It illustrates key features of the mock-up. The mock-up itself is **not** final or comprehensive.

A goal of this early mock-up is to inform members of the public of our current thinking on the types and organization of data for submission of “basic results,” including data items and dropdown menu choices. There are two ways to explore the site:

- Click through the two fixed (read-only) sample results records
- Create your own “practice” result record (Note: Practice records are accessible to other current users of the site. All practice records will be deleted nightly)

Comments and feedback on the basic structure of the results information we are collecting will be considered during the iterative development of the system. Please do **not** comment on the user interface or usability, as we will address these issues in later iterations. Submit all comments using the form at <http://prsinfo.clinicaltrials.gov/rrs-comments.html>.

Notes on the Interactive Early Mock-up

1. Requirements for basic results information have not been determined. The presence of a data item in this interactive early mock-up does not necessarily imply that it will be required.
2. This mock-up does not address the public display of results. The public display will be the subject of a future posting.

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Main Menu

[Create Results Record](#)
[Results List](#)

y Mock-up : TEST

Results Registration System (Data Entry Mock-up)

Create Results Record

Enter NCT ID and the creator name, then click Lookup to see identifying information. If you wish to start a new result record, then click Create to create the corresponding results record.

NCT ID:

[Search on ClinicalTrials.gov](#)

Creator Name:

View the “brief title” of the study for the NCT ID provided.

Find studies registered at ClinicalTrials.gov.

Create a new results record.

Lookup

Create


Cancel

Creating a New Results Record

To create a “practice” results record in the mock-up, click on “Create Results Record.” In the actual system, this step will be conducted through your usual ClinicalTrials.gov Protocol Registration System (PRS) account.

The Create Results Record page allows users to generate a practice results record in this mock-up. Click “Create” after entering a valid NCT number from the ClinicalTrials.gov registry and any text in the “Creator Name” field.

Note that practice records are visible and modifiable by other current users. In the actual system, users will only have access to those records for which they are the owner. Also, all “practice” records will be deleted each night.

RRS Data Entry Mock-up : TEST
<i>ClinicalTrials.gov</i> Results Registration System (Data Entry Mock-up)
Main Menu
<div>Create Results Record Results List</div> 

Exploring an Existing Results Record

To explore a results record in the mock-up, click on “Results List.” In the actual system, this step will be conducted through your usual PRS account.

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)
[Main Menu](#) [Create Results Record](#)

Fixed (read-only)
examples illustrating
data entry for two
common trial designs.

Existing Result Records

	Result Creator	Organization	Protocol ID	NCT ID	Last Modified
Edit	NLM parallel example	Fictional Data Provider	1234	NCTZZZZZZZZZ	May 16, 2008
Edit	NLM crossover example	Fictional Data Provider	5678	NCTWWWWWWWW	May 16, 2008

Exploring Existing Results Records

This page provides a menu to access results records available in the mock-up. The list includes two fixed (read only) fictitious examples of results records and any records entered by users on that day. This page is not intended for comment and is simply a menu to access examples. All results records must have been registered in ClinicalTrials.gov, thus each results record identifier ("Protocol ID") will have a corresponding unique registration identifier ("NCT ID").

The user can click "edit" next to a record to review or enter information. For example, clicking "edit" next to "NLM crossover example" will take the user to the "edit results record" page for this study.

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Edit Results Record

[Main Menu](#) [Results List](#)

Information Provided By: Fictional Data Provider

Unique Protocol ID: 5678

Brief Title: A Sample Study with a Crossover Design

NCT ID: [NCTWWWWWWWW](#)

Data automatically imported (pre-populated) from the corresponding ClinicalTrials.gov registration record, NCTWWWWWWWW.

Placeholders for an FDAAA 801 "basic results" information.

"Period 1" is pre-listed by system. Additional discrete "periods" may be added, as needed. Two additional periods have been entered for this example.

The first six baseline characteristics are pre-listed by the system. Two additional characteristics have been entered for this example.

Pre-populated from registration record.

Edit	Result Point of Contact:	[To Be Developed] Name/Official Title: Organization: Phone: Ext: Email:
	Certain Agreement:	[To Be Developed]
Edit	Participant Flow:	Trial Period: Period 1 Trial Period: Period 2 Trial Period: Period 3
Edit	Baseline Characteristics:	<ul style="list-style-type: none"> • Age [Time Frame: Enrollment] • Age Categories [Time Frame: Enrollment] • Gender [Time Frame: Enrollment] • Race [Time Frame: Enrollment] • Ethnicity [Time Frame: Enrollment] • Region of Enrollment [Time Frame: Enrollment] • Menopausal Status [Time Frame: Enrollment] • Hot Flashes [Time Frame: Enrollment]
Edit	Limitations and Caveats:	[To Be Developed]
Edit	Outcome Measures:	<ul style="list-style-type: none"> • Primary Measure: (DATA) Change in hot flash score [Time Frame: 12 weeks]

Edit Results Record Page - Overview of data in results record pre-populated from the fictitious ClinicalTrials.gov registry record, NCTWWWWWWWW. The user can enter data by clicking the "edit" next to "Participant Flow." In the actual system, it will be possible to complete modules in any sequence.

ClinicalTrials.gov Results Registration System

User-specified “comparison groups.” These columns will default to “arms,” but may be modified as appropriate.

Participant Flow for NCTWWWWWW

OK

[Add New Period](#)[Edit Comparison Groups](#)

If relevant, please describe how and why the number of subjects enrolled differs from the number to start the first period.

70 women between the ages of 40 and 65 who were having hot flashes were recruited for the study at family practice clinics in Washington, DC. 8 were excluded from the study due to concomitant conditions.

Period	Milestone		placebo then drug 10mg	drug 10mg then placebo
Edit Period1	Started Period	Number subjects started period	33	29
		Comments	Period one is a 1-week pre-treatment period to assess baseline measurements.	Period one is a 1-week pre-treatment period to assess baseline measurements.
	Completed	Number subjects completed period	29	24
		Number subjects not completing period	4	4
		Reason: Other	4	4
		Reason: Adverse Events		
		Comments (Describe other reasons in comments.)	Not specified	Not specified

Any number of “milestones” may be reported for a period, as needed.

Participant Flow

Like a [CONSORT flow diagram](#)^{*}, this page is used to enter information about the progress of subjects through the different “periods” of a study, but in a tabular format rather than a diagram.

Each “period” always begins and ends with— (1) Started Period and (2) Completed Period, respectively. Many studies will have just one period, though some, for example, a crossover study, might have two or more periods.

^{*} See figure on p. 660: [Moher D et al. Ann Intern Med. 2001;134:657-62.](#)

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Participant Flow for Interventional Trial (NCTWWWWWWW)

This is a fixed example and cannot be changed

Explanatory text regarding events prior to assignment to arm or comparison groups.

NCTWWWWWWW Result

If relevant, please describe how and why the number of subjects enrolled differs from the number to start the first period.

70 women between the ages of 40 and 65 who were having hot flashes were recruited for the study at family practice clinics in Washington, DC. 8 were excluded from the study due to conc

Period	Milestone	placebo then drug 10mg	drug 10mg then placebo
Period1	Number subjects started period	33	29
Start	Comments	Period one is a 1-week pre-treatment measurements.	Period one is a 1-week pre-treatment period to assess baseline measurements.
Add Milestone	Number subjects achieved milestone		
Washout	Comments		
Run-in	Number subjects completed period	29	24
Transition	Number subjects not completing period	4	4
Received Intervention	Add Reason		
Completed Intervention	Reason:	4	4
Other	Reason:		
	Adverse Events	Not specified	Not specified
	Adverse Events		
	Lost to Follow-up		
	Withdrew Consent		
	Protocol Violation		
	Unsatisfactory Therapeutic Effect		
	Other		

OK Cancel

Controls for manipulating Rows (e.g., "Milestones").

Menu of milestones that may be included in any single period.

Menu of reasons why subjects did not complete this period.

Participant Flow (continued)

Milestones may be added to a period and described using the dropdown menu (e.g., "washout"). Free-text fields facilitate annotation of each milestone.

The Completed Period consists of two pre-listed milestones: (1) "Number subjects completed period" and (2) "Number subjects not completing period." The latter milestone may be further subdivided into different categories of reasons why subjects did not complete the period by using the dropdown menu (e.g., "adverse events"). A comment section is provided for additional reasons.

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Baseline Measures for NCTWWWWWWW

This is a fixed example and cannot be changed

OK

[Add New Baseline Measure](#)
[Edit Comparison Groups](#)
[Edit](#)

Age [TimeFrame: Enrollment] [MeasureUnit: Years]	Total		drug 10mg to placebo		placebo to drug 10mg	
	median	full range	median	full range	median	full range
Age	53.9	36.6 to 77.1	52.3	41.1 to 77.1	56.7	36.6 to 77.0

[Edit](#)

Age Categories [TimeFrame: Enrollment] [MeasureUnit: Number of Subjects]	Total		drug 10mg to placebo		placebo to drug 10mg	
	number		number		number	
>=65 years						
<=18 years						

[Edit](#)

Gender [TimeFrame: Enrollment] [MeasureUnit: Number of Subjects]	Total		drug 10mg to placebo		placebo to drug 10mg	
	number		number		number	
Female	62		33		29	
Male						
Other						
Unspecified / Unknown						

Baseline Measures

This page is an overview of baseline measures for a results record. Data for each baseline measure are entered as a table. Tables can be customized by the user to describe the characteristics of the subjects in a trial. There are columns for groups of participants: "Total," and one column for each arm. Arm information will be pre-populated from the registry. However, if it is not available or is not appropriate for the particular trial, then column headings can be entered by the user. The column heading can be edited by selecting "Edit Comparison Groups."

Each row will represent one baseline characteristic. Commonly used characteristics are pre-listed and include Age (as a continuous variable), Age (as a categorical variable), Gender, Race, Ethnicity, and Region of Enrollment. Any tables and rows appropriate to a study may be used. However, specific requirements have not been determined.

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Baseline Demographics

This is a fixed example and cannot be changed

Edit Baseline Demographics for NCTWWWWWWWW

Baseline Measure: Age

Time Frame: Enrollment

Measure in unit: Years

	Total		drug 10mg to placebo		placebo to drug 10mg	
	median	full range	median	full range	median	full range
Age	53.9	36.6 to 77.1	52.3	41.1 to 77.1	56.7	36.6 to 77.0

OK

Cancel

Edit Baseline Demographics – Pre-set Baseline Measure

This page demonstrates the pre-set table for Age (as a continuous variable). Although Age is listed with a unit of “years,” the unit can be changed to one that is more appropriate for the study (e.g., months).

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Baseline Demographics

This is a fixed example and cannot be changed

Edit Baseline

/WWW

Baseline Measure: Time Frame: Measure in unit: Menu –
“types of
measurement.”Menu –
“measures of
dispersion.”

Total		drug 10mg to placebo		placebo to drug 10mg	
		mean	standard deviation	mean	standard deviation
mean	standard deviation				
number					
mean	standard deviation				
median	inter-quartile range				
least square mean	full range				
	standard error				

OK

Cancel

Edit Baseline Demographics – New Baseline Measure

Users can “Add New Baseline Measure(s)” from the Baseline Measures page (page 8) to enter other measures of relevance to the particular study. The user can enter descriptive information about the measure: the name of the baseline measure, time frame and the units of the measure. Users can also indicate the type of measurement (e.g., mean, median, etc), a measure of dispersion (if a continuous measure) and names of categories (if a categorical measure). The user can then enter the data into the appropriate cells of the newly constructed table.

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry)

Outcome Measures for NCTWWWWWWW

This is a fixed example and cannot be changed

Note: "Comparison groups," previously defined by order of intervention administered or arms in the Baseline Characteristics table (e.g., "drug 10 mg to placebo"), are redefined as "all subjects receiving the intervention at 12 weeks" in the Outcome Measures table.

[NCTWWWWWWW Result](#) [Add Measure](#)
[Protocol](#)

Measure List

Measure

Measure Description

Measure Summary

Measure Analysis

[Edit](#)
[Delete](#)

Measure:

	Total	drug 10mg		placebo	
Number Subjects Analyzed	39	20		19	
Analysis Population Details	Each comparison group includes all subjects receiving the intervention at 12 weeks				
	drug 10mg		placebo		
	mean	standard deviation	mean	standard deviation	
Primary Measure: Change in hot flash score [Time Frame: 12 weeks]	-1.7	8.4	3.4	5.2	
Analysis	Groups Compared:		<input checked="" type="checkbox"/> drug 10mg <input checked="" type="checkbox"/> placebo		
	Statistical Test of Hypothesis:		PValue: <0.03 Method: 2 sided T test		
	Method of Estimation:				

Outcome Measure List

This page is an overview of the primary and secondary outcome measures including information describing the measure and analysis of the measure. The primary and secondary outcome measures are pre-populated from the registry record and may be edited. First, a user may want to edit information relating to the measure itself.

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Return to "Edit Result Record."

Add a new measure.

Outcome Measure for NCTWWWWWWWW

This is a fixed example and cannot be changed

View corresponding registration record (NCTWWWWWWWW) at ClinicalTrials.gov.

NCTWWWWWWWW Result All Measures NCTWWWWWWWW

Protocol

Measure List **Measure** Measure Description Measure Summary Measure Analysis[Edit](#)**Measure:** Change in hot flash score [Time Frame: 12 weeks]**Measure Description:** Hot flashes were assessed using the model of Lopenzi et al. For each 24-hour period, patients noted the number of hot flashes and assigned a graded intensity to each hot flash (mild [1], moderate[2], severe[3], or very severe[4]). The hot flash score was calculated by multiplying the number of hot flashes per week by the average intensity. A 50% reduction in hot flash score from baseline was considered a response.[Edit](#)**Measurement Summary:**

	Total	drug 10mg		placebo	
Number Subjects Analyzed	39	20		19	
Analysis Population Details	Each comparison group includes all subjects receiving the intervention at 12 weeks.				
	drug 10mg		placebo		
	mean	standard deviation	mean	standard deviation	
Primary Measure: Change in hot flash score [Time Frame: 12 weeks]	-1.7	8.4	3.4	5.2	

Add Analysis Zero or more analyses may be entered for this outcome measure.[Edit](#)
[Delete](#)

Analysis:	Groups Compared:	<input checked="" type="checkbox"/> drug 10mg <input checked="" type="checkbox"/> placebo
	Statistical Test of Hypothesis:	PValue: <0.03 Method: 2 sided T test
	Method of Estimation:	

Outcome Measure

This page provides users with a menu to edit a specific measure, including information related to the statistical analysis. The user can select "edit" to navigate to the next data entry screen.

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Edit Outcome Measure

This is a fixed example and cannot be changed

[Protocol](#)

Measure List Measure **Measure Description** Measure Summary Measure Analysis

Type of Measure: ☒primary ☐secondary

Measure: Enter a brief label for the assessments reported by the measure data.

Change in hot flash score

Measure Description: If needed, describe the tools used to collect or derive the measure data.
If the measure is not commonly accepted, describe what was done to collect assessments, how frequently were assessments made, and the measurement tool. Also, if relevant, describe methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).

Hot flashes were assessed using the model of Lopenzi et al. For each 24-hour period, patients noted the number of hot flashes and assigned a graded intensity to each hot flash (mild [1], moderate[2], severe[3], or very severe[4]). The hot flash score was calculated by multiplying the number of hot flashes per week by the average intensity. A 50% reduction in hot flash score from baseline was

Time of Analysis:

12 weeks

OK

Cancel

Edit Outcome Measure

This page includes pre-populated information from the registry for the type, measure, and time of analysis. The measure can be edited and a detailed description of how the measure was assessed can be provided (e.g., a description of the validated instrument utilized for assessment). The time of analysis can also be edited, if necessary.

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Outcome Measure for NCTWWWWWWWW

This is a fixed example and cannot be changed

NCTWWWWWWWW Result All Measures NCTWWWWWWWW

Protocol

Measure List **Measure** Measure Description Measure Summary Measure Analysis[Edit](#)

Measure: Change in hot flash score [Time Frame: 12 weeks]

Measure Description: Hot flashes were assessed using the model of Lopenzi et al. For each 24-hour period, patients noted the number of hot flashes and assigned a graded intensity to each hot flash (mild [1], moderate[2], severe[3], or very severe[4]). The hot flash score was calculated by multiplying the number of hot flashes per week by the average intensity. A 50% reduction in hot flash score from baseline was considered a response.

[Edit](#)

Measurement Summary:	Total		drug 10mg		placebo
	Number Subjects Analyzed		39	20	19
	Analysis Population Details		Each comparison group includes all subjects receiving the intervention at 12 weeks.		
	drug 10mg			placebo	
	mean		standard deviation	mean	standard deviation
	Primary Measure: Change in hot flash score [Time Frame: 12 weeks]		-1.7	8.4	3.4
				5.2	

Add Analysis Zero or more analyses may be entered for this outcome measure.[Edit](#)[Delete](#)

Analysis:	Groups Compared:	<input checked="" type="checkbox"/> drug 10mg <input checked="" type="checkbox"/> placebo
	Statistical Test of Hypothesis:	PValue: <0.03 Method: 2 sided T test
	Method of Estimation:	

Outcome Measure

After completing the Edit Outcome Measure page, the user is returned to the menu page that allows for editing measure and analysis information. The user may then edit relevant summary information for the measure by selecting "edit" (next to "Measurement Summary").

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Edit Measure Summary for NCTWWWWWWW

This is a fixed example and cannot be changed

Primary Measure: Change in hot flash score [Time Frame: 12 weeks]

[Protocol](#)
[Measure List](#) [Measure](#) [Measure Description](#) **[Measure Summary](#)** [Measure Analysis](#)

	Total	drug 10mg	placebo
Number Subjects Analyzed	39	20	19
Analysis Population:	Describe the analysis population. Include, if relevant, information on why subject measurements were excluded, such as Last Observation Carried Forward; or the definition used for intention to treat. Each comparison group includes all subjects receiving the intervention at 12 weeks.		
How do you enter: Continuous Data Categorical Data Time To Event Data			
Add Category	Edit	Edit	
mean	mean	standard deviation	standard deviation
standard deviation			
standard deviation			
inter-quartile range			
full range			
standard error			
Change in			
Time Frame: 12			
weeks]	-1.7	8.4	3.4
OK Cancel			

Online help for different data types.

Controls for manipulating columns ("comparison groups").

Edit comparison group label.

Menu – "types of measurement."

Add new category for "categorical data."

+ X ← →
 "Add" "Delete" "Move left" "Move right"

Edit Measure Summary

This page allows users to specify the arms/groups that were compared in the analysis. The comparison groups may be different than the arms of the study. The arms designated in the registry will be the default display, however these groups (columns) can be edited by changing the labels and adding or deleting groups (columns) in order to reflect the analysis population. Any additional information related to the population analyzed can also be provided as free text. The units of measurement, values for each cell, and a measure of dispersion can be provided, as appropriate.

After the measure summary page is completed, the user can select "OK" and return to the Outcome Measure page to "Add Analysis." The number of analyses that are entered for each outcome measure is determined by the user.

RRS Data Entry Mock-up : TEST

ClinicalTrials.gov Results Registration System (Data Entry Mock-up)

Outcome Measure for NCTWWWWWWWW

This is a fixed example and cannot be changed

NCTWWWWWWWW Result All Measures NCTWWWWWWWW

Protocol

Measure List **Measure** Measure Description Measure Summary Measure Analysis[Edit](#)

Measure: Change in hot flash score [Time Frame: 12 weeks]

Measure Description: Hot flashes were assessed using the model of Lopenzi et al. For each 24-hour period, patients noted the number of hot flashes and assigned a graded intensity to each hot flash (mild [1], moderate[2], severe[3], or very severe[4]). The hot flash score was calculated by multiplying the number of hot flashes per week by the average intensity. A 50% reduction in hot flash score from baseline was considered a response.

[Edit](#)

Measurement Summary:	Total		drug 10mg		placebo	
	Number Subjects	20			19	
	Analysis Population	Each comparison group includes all subjects receiving the intervention at 12 weeks.				
	drug 10mg			placebo		
		mean	standard deviation		mean	standard deviation
Primary Measure: Change in hot flash score [Time Frame: 12 weeks]		-1.7	8.4		3.4	5.2

Add a new analysis for this specific measure. Each measure may report any number of analyses, as needed.

Add Analysis Zero or more analyses may be entered for this outcome measure.[Edit](#)[Delete](#)

Analysis:	Groups Compared:	<input checked="" type="checkbox"/> drug 10mg <input checked="" type="checkbox"/> placebo
	Statistical Test of Hypothesis:	PValue: <0.03 Method: 2 sided T test
	Method of Estimation:	

Outcome Measure

After completing the Edit Measure Summary page, the user is returned to the menu page that allows for editing measure and analysis information. The user may then edit relevant analysis information by selecting "Edit" next to "Analysis" to navigate to the next data entry screen.

RRS Data Entry Mock-up : TEST				
ClinicalTrials.gov Results Registration System (Data Entry Mock-up)				
Edit Analysis for NCTWWWWWWWW				
This is a fixed example and cannot be changed				
Primary Measure: Change in hot flash score [Time Frame: 12 weeks] Protocol				
<div>Measure List</div> <div>Measure</div> <div>Measure Description</div> <div>Measure Summary</div> <div>Measure Analysis</div>				
Comparison:		What groups included in the comparison? <input checked="" type="checkbox"/> drug 10mg <input checked="" type="checkbox"/> placebo If relevant, provide additional details about the comparison, such as order of included groups or a comparison of one group to more than one other group. [To Be Developed]		
Statistical Test of Hypothesis:		P-Value: <0.03 If desired, provide additional information, such as a description of the null hypothesis or details of power calculation. Tested for non-inferiority or equivalence (Select No if tested for superiority): <input type="button" value="v"/> If relevant, please describe details of power calculation, definition of non-inferiority margin, and other key parameters.		
Method of Estimation:		Method: 2 sided T test <input type="button" value="v"/> If other, please specify: Describe any other relevant information, such as adjustments or degrees of freedom.		
		95 % Confidence Interval: to What parameter, if any, did you estimate (e.g., Odds Ratio)? <input type="button" value="v"/> If other, please specify: Estimated Value: Units: Standard Error <input type="button" value="v"/> : +/- Describe any other relevant information.		
<div>OK</div> <div>Cancel</div>				

Designate groups compared.

Provide statistical test information.

Describe estimation method.

Edit Analysis

The analysis is comprised of three basic categories of information: designation of the groups (arms) being compared, statistical test information and the method of estimation.

RRS Data Entry Mock-up : TEST				
ClinicalTrials.gov Results Registration System (Data Entry Mock-up)				
Edit Analysis for NCTWWWWWWWW				
This is a fixed example and cannot be changed				
Primary Measure: Change in hot flash score [Time Frame: 12 weeks]				Protocol
Measure List	Measure	Measure Description	Measure Summary	Measure Analysis
Comparison:		What groups included in the comparison?		
		<input checked="" type="checkbox"/> drug 10mg <input checked="" type="checkbox"/> placebo If relevant, provide additional details about the comparison, such as order of included groups or a comparison of one group to more than one other group. [To Be Developed]		

Edit Analysis - Comparison

The user will be asked what comparison they are reporting. If the trial has two comparison groups, then both boxes should be checked. If there are more than two groups, the user should click those groups that are used in the comparison.

Enter p-value.

P-Value: <0.03

If desired, provide additional information, such as a description of the null hypothesis or details of power calculation.

Tested for non-inferiority or equivalence (Select No if tested for superiority):
 If relevant, please describe details of power calculation, definition of non-inferiority margin, and other key parameters.

Identify if tested for non-inferiority or equivalence.

Yes
No

Method: 2 sided T test
 If other, please specify:
 If relevant, please provide additional information, such as adjustments or degrees of freedom.

Enter confidence (95% is default).

95
 What parameter is being estimated?

Estimate:
 Standard Error
Standard Deviation

Method of Estimation:

Wilcoxon (Mann-Whitney)
Kruskal-Wallis
McNemar
Log rank
Chi-squared
Corrected Chi-squared
Fisher exact
ANOVA
ANCOVA
Sign test
Cochran-Mantel-Haenszel
Mantel Haenszel
Logistic regression
Linear regression
Cox regression
1 sided T test
2 sided T test
Other

Units:
 Estimate (e.g., Odds Ratio)?
 Odds Ratio (OR)
Risk Ratio (RR)
Risk Difference (RD)
Hazard Ratio (HR)
log OR
log RR
log HR
mean difference (net)
mean difference (final values)
median difference (net)
median difference (final values)
slope
Other

Provide confidence interval.

OK Cancel

Edit Analysis Page – Statistical Test and Method of Estimation

The user can enter a p-value, if desired. If a p-value is entered, the user should use the pull down menu to select the name of the statistical test used. The user should also use the pull down menu to indicate if the analysis conducted is a test of non-inferiority or equivalence. Free text boxes provide space to comment on specific aspects of the analyses, as noted. The user can then enter a confidence interval, if desired. 95% is provided as the default confidence interval, however this can be edited. If a confidence interval is entered, the user should use the pull down menu to select the method of estimation used. This section includes places for noting the interval and for providing other relevant comments.